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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/620,794

07/15/2003

Jeff J. Staggs

1100

7590

04/11/2006

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,794

Applicant(s)

STAGGS, JEFF J.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1 and 4-6 are presented for examination.

Applicant's amendment filed December 30, 2005 has been received and entered.

Accordingly, the rejection made under 35 USC 112, second paragraph as set forth in the previous Office action dated June 1, 2005 at pages 4-5 as applied to claim 6 is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-6 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacteria infections caused by *Staph aureus* with the administration of black pepper, does not reasonably provide enablement for treating all infectious diseases and bacteria infections caused by various gram-negative and gram-positive bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

As of record, for reasons of record as set forth in the previous Office action dated June 1, 2005 at pages 2-4 as applied to claims 1 and 4-6.

Applicant's remarks regarding the instant specification is enabled to both produce and apply any of the formulations toward the treatment of disease as specifically described or to those related are not persuasive since the applicant's instant specification only shows results using black pepper lotion administered to a woman with a bacterial infection caused by a drug-resistant strain of Staph aureus is not sufficient to show the instant invention is effective against all drug-resistant bacteria without any experimental data showing the other drug-resistant bacteria were eradicated by the instant black pepper.

The rejection made under 35 USC 112, first paragraph is adhered to.

Claims 1 and 4-6 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are again rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi et al., "Antibacterial and antitumor activities of piperine from black pepper", Kenkyu Kiyo-Tokyo Kasei Daigaku, 1985, Vol. 25, pp. 201-203 or Dorman et al., "Antimicrobial agents from plants: antibacterial activity of plant volatile oils", Journal of Applied Microbiology, 200, Vol. 88, No. 2, pp. 308-316, all of record, for reasons of record as set forth in the previous Office action dated June 1, 2005 at pages 5-6 as applied to claims 1 and 4.

Applicant's remarks regarding the prior art, Yamaguchi et al. or Dorman et al., does not teach the black pepper is effective against drug-resistant bacteria are not persuasive since the prior art does teach black pepper as possessing antibacterial activity as various bacteria (gram-negative and gram-positive) because any of these bacteria can become drug-resistant.

The rejection made under 35 USC 102 is adhered to.

Claims 1 and 4 are not allowed.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al., "Antibacterial and antitumor activities of piperine from black pepper", Kenkyu Kiyo-Tokyo Kasei Daigaku, 1985, Vol. 25, pp. 201-203 or Dorman et al., "Antimicrobial agents from plants: antibacterial activity of plant volatile oils", Journal of Applied Microbiology, 200, Vol. 88, No. 2, pp. 308-316, all of record, for reasons of record as set forth in the previous Office action dated June 1, 2005 at pages 6-8 as applied to claims 5 and 6.

Applicant's remarks regarding prior art, Yamaguchi et al. or Dorman et al., does not teach the administration of black pepper to treat cellulitis or necrotizing fasciitis (flesh eating disease) are not persuasive since the applicant does not provide any test results or experimental data showing the black pepper is effective in the treatment of these two bacterial infection diseases.

The rejection made under 35 USC 103 is adhered to.

Claims 5 and 6 are not allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

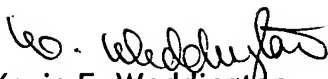
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
April 6, 2006